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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,346	07/20/2001	Lance E. Steward	D-2885CIP	2952

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,346	STEWARD ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Sequence Rules

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the* "Sequence listing" and in the text of the description and *claims* whenever described. For example, the appropriate SEQ ID NO must be recited in claim 9. Note further that although only amino acid sequence of 4 or more require their own SEQ ID NO, 37 CFR 1.822(o) states that a sequence made up of *one or more noncontiguous segments* of a larger sequence ***or*** *segments from different sequences* shall be presented as a separate sequence (i.e., as it relates to claim 10). See MPEP 2422 & 2431. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Note that failure to respond to both the requirements for sequence compliance and the restriction requirement below will be held as *nonresponsive*, and may result in *abandonment* of this application.

Election/Restriction

2. Applicant's election with traverse of Group I (claims 1-2 & 4-13 for "enhanced" biological persistence, versus claims 1 & 3-13 as incorrectly recited in the 9/30/03 restriction requirement) in Paper No. 11/03/03 is acknowledged. The traversal is on the ground(s) that "since all of the claims of Groups I to IVX (*sic*) relate to changing the biological persistence of botulinum toxins by altering the amino acid sequence of the toxins there would be no serious burden placed upon the Examiner to perform a search encompassing all claims of Groups I to IVX (*sic*)". This is not found persuasive because each modified neurotoxin is structurally and physically unique as illustrated by their own unique amino acid sequence, in which different neurotoxins interact with different proteins, and in which the different claimed methods have different goals requiring different starting material and different method steps; and for the reasons made of record in Paper No: 9/30/03.

Because the previous restriction requirement failed to require election for modifications of specific botulinum toxins, a new restriction requirement is necessitated because the claims are ultimately directed toward different and distinct modified botulism toxins (i.e., A, B, C1, C2, D, E, F & G) or tetanus toxin, which represent patently distinct inventions as illustrated by their unique sequences. Thus, claims 1-2 & 4-13 are further restricted to a single specific botulism serotype (i.e., A, B, C1, C2, D, E, F **or** G, or tetanus toxin). Should the claims be amended to reflect an individual SEQ ID NO, the claims would then be further restricted to a specific SEQ ID NO. Note that should modified botulinum toxin type A be elected, claims 17 & 39-40 may be rejoined with the invention of Group I provided they are amended to enhancing a specific and assayable biological persistence and recite the appropriate specific modification limited to botulinum type A. In summary, this is a restriction requirement, and not a species election, where each mutated botulism toxin, etc. constitutes a separate and distinct invention, as illustrated by their unique immunologically distinct amino acid sequence, different functional and structural characteristics, and different bacterial strain from which each different serotype is isolated.

Because these inventions are distinct for the reasons given above, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined, for both a serotype and a SEQ ID NO (if so amended), even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
February 5, 2003

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